GEORGETOWN UNIVERSITY | MedStar Health

Social and Behavioral Protocol Template

To be used for Social and Behavioral studies only. If this study is using investigational drugs and medical devices, special diets and/or radioactive materials please complete the Biomedical Protocol Template instead.

Please answer every question, and mark N/A if not applicable. Please submit this form plus copies of required documents such as consent forms, questionnaires, surveys, interview scripts, subject recruitment materials, and the responsible participant form. If you have questions about this form, please contact the appropriate IRB office.

I. BASIC INFORMATION

1. Title of Study Include the full protocol title
Assessing the feasibility of web-based insomnia treatment among prostate cancer survivors
2. Principal Investigator
Name: Traci Bethea, PhD, MPA
Institutional Affiliation:Georgetown
Department:Oncology
Phone Number:202-687-9372
Email:tb988@georgetown.edu
3. Location(s) of Research Describe the sites/locations* for the research and any site-specific regulations or customs affecting the research at those sites. *Sites: institution or place where the research is conducted. Location: specific state or country. In addition, describe any local scientific/ethical reviews completed for those sites and attach the ethics review in the SmartForm. Information on international laws and regulations governing human research is available at: https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html
Office of Minority Health and Health Disparities Research.
4. Anticipated dates of research Includes contact with human subjects and analysis of identifiable data. Applications to the IRB must be submitted **prior** to any interactions with human subjects.

Start Date: 8/15/2024	End Date: 8/14/2025

II. STUDY INFORMATION

1. Version Number and Date

Keep a version of this document in a Word format. Version control is important when protocols are being created or revised; it helps to track changes and identify when key decisions were made along the way. Version control allows the study team and regulatory groups to identify which version of a protocol was approved and applicable at a particular time. Versions can be documented by date and/or chronologic numbering each time you submit a modified protocol document. If you have to submit revisions to the protocol, revise this document and note a new version below.

Revision #	Version Date	Summary of Changes	Consent Change?
Initial V1		NA	NA
V2	May 2, 2025	Update for compenstation when no technology-related data collection available	☐ Yes ☒ No
V3			☐ Yes ☐ No
V4			☐ Yes ☐ No

2. Study Specific Abbreviations and Definitions

CBT-I – cognitive-behavioral therapy for insomnia
DEXA – dual energy x-ray absorptiometry
ISI – Insomnia Severity Index
NCCN – National Comprehensive Cancer Network
OMH – Office of Minority Health and Health Disparities Research
PCS – prostate cancer survivor
PRO – patient-reported outcome
RCT – randomized controlled trial
SHUTi – Sleep Healthy Using The Internet
SIESTA-P Study – Assessing the feasibility of web-based insomnia treatment among prostate cancer survivors study

3. Purpose of Study

Provide a concise explanation of the research project you are undertaking, including:

- Purpose, objectives, or hypothesis for the study
- What you hope to learn from the research

The purpose of this pilot study is to investigate a web-based cognitive behavioral therapy for insomnia (CBT-I) treatment among Black prostate cancer survivors and to collect preliminary data, including effect sizes, for a future appropriately sized study. Thus, the objectives of this study are to:
1. Assess the feasibility of conducting a RCT using a web-based CBT-I intervention (Sleep Healthy Using the Internet, SHUTi) among Black prostate cancer survivors;
2. Assess the acceptability of SHUTi among Black prostate cancer survivors;
3. Assess the efficacy of SHUTi among Black prostate cancer survivors; and
4. Assess the impact of SHUTi on non-insomnia patient-reported outcomes (PROs) among Black prostate cancer survivors.

4. Background

Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how it will add to existing knowledge.
State how your research project is a logical step in studying the topic.
Note: this section should be limited to only information directly related to the research questions and objectives. Do not include your full dissertation proposal. Include a synopsis of the most immediately relevant previous studies, if any, that have been conducted. Include relevant research references.

There is a non-pharmacological internet-based self-administered treatment for insomnia called SHUTi (Sleep Healthy Using the Internet) that has been shown to be effective in multiple randomized trials among populations that were predominantly White. There were few Black participants and there is little evidence of the effectiveness of this treatment among Black men. The goal of this study is to assess the feasibility, acceptability, and efficacy of a web-based cognitive behavioral therapy for insomnia (CBT-I; SHUTi) among Black prostate cancer survivors, an understudied population with unique sleep challenges. Multiple clinical trials have demonstrated efficacy for SHUTi in a variety of populations. However, few studies have included appreciable numbers of Black participants or cancer survivors. In an RCT among middle-aged and older Black women, both the standard version and a culturally-tailored version of SHUTi were associated with clinically significant improvements in insomnia symptoms, although engagement was higher among participants who received the tailored intervention.
Prostate cancer has the highest incidence rate and second highest mortality rate among men in the U.S. with a highest burden of both incidence and mortality among Black men compared to men of other racial/ethnic groups. Incidence rates in DC (131.3 per 100,000) and Maryland (132.7 per 100,000) exceed the national average (109.9 per 100,000). Insomnia is a risk factor for poor physical, cognitive, and psychosocial outcomes, including

depression, anxiety, frailty, and diminished cognitive function, especially among cancer survivors. Although cancer treatment, including androgen deprivation therapy, may increase insomnia symptoms and the prevalence of insomnia among prostate cancer survivors is estimated to be 25-39%, few studies have examined treatment of insomnia in this population and few have included collection of objective sleep data. Insomnia is associated with greater symptom burden (e.g., greater depression, greater distress, greater anxiety, greater fatigue, poorer cognition) among prostate cancer survivors, so treating insomnia may provide an opportunity to improve well-being in this population.
CBT-I has demonstrated substantial and persistent improvements in insomnia severity among cancer survivors such that the National Comprehensive Cancer Network (NCCN) recommends CBT-I "as the preferred treatment for insomnia." Trials to develop and test web-based and digital CBT-I interventions have shown non-inferiority to in-person administration by a trained therapist and increase availability of insomnia treatment to more patients. Recent NCCN guidelines note that improving sleep may provide additional benefits by resulting in less fatigue, better mood, better quality of life, and improved survival. CBT-I trials have also observed improvements in symptom burden regardless of delivery modality (i.e., in-person, via telephone, digitally/via the internet). SHUTi has demonstrated efficacy among breast cancer survivors and both the standard version of SHUTi and a culturally-tailored version of SHUTi demonstrated efficacy among middle-aged and older Black women. However, to date, this accessible and interactive intervention has not been investigated among prostate cancer survivors. Thus, the Assessing the feasibility of web-based insomnia treatment among prostate cancer survivors study (SIESTA-P Study) will provide preliminary data to help address these gaps in the literature. Further, little is know about biomarkers of the health impact of CBT-I, so the SIESTA-P Study will collect both blood samples and digital biomarkers.

5. Study Intervention(s)

Describe the study intervention(s) if any. Indicate NA if there are no interventions. Note: Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

The study intervention, SHUTi, is a web-based CBT-I treatment program that involves participation in six modules called Cores. Each participant randomized to the intervention arm will log in to the six modules of their assigned treatment program over a 6-9 week period. The program is designed to provide tailored instructions about how to improve a person's sleep. The Cores are completed one at a time in order and each Core is expected to take 45-60 minutes to complete. Each Core contains information and exercises designed to help change behaviors and thoughts that can contribute to sleep problems. Participants will receive automated emails encouraging them to complete tasks. Participants will be asked to complete weekly to dos and enter daily sleep diaries to track their sleep. After each module, participants will need to complete 5 sleep diaries to proceed to the next module (~2 minutes to complete each).

6. Procedures Involved

a. Select the methods that will be employed in this study (select all that apply):

☐ Audio Recording
☐ Video Recording
☐ Psychophysiological Recording
☐ Behavioral Observations
☐ Educational Record Review*
☐ Behavioral Interventions
☐ Focus Groups
☐ Record Review – Other
☐ Interviews
☒ Specimen Collection or Analysis
☒ Surveys and/or Questionnaires
☒ Mobile Applications
☐ Psychometric Testing
☐ Secondary Data Analysis
☒ Other Social-Behavioral Procedures: **Staff measurement (e.g., anthropometrics, blood pressure)**
*Records obtained from schools or other educational institutions

b. Provide the following:
   - a description of the activities that will be conducted throughout the course of the study, including any interaction, how intervention will be used, observation, or experiment involving human subjects, including control groups when applicable.
   - a description of the strategy you will adopt to obtain and retain contact information as well as how you will re-contact subjects in the event any follow-up is planned.
   - List any 3rd-party service providers used for data collection, transcription, analysis, etc.

We will conduct a 2-arm pilot RCT among Black adults diagnosed with invasive prostate cancer with symptoms of insomnia based on the Insomnia Severity Index. The study will recruit 40 participants and randomize them 1:1 to the SHUTi program (i.e., intervention) or web-based sleep hygiene materials (i.e., usual care) after study enrollment data collection. The service provider for the SHUTi program - including both the intervention and usual care conditions - is the University of Virginia's Center for Behavioral Health and Technology. Study enrollment data collection will include staff measurement of anthropometrics (i.e., height; weight; neck, waist, and hip circumferences; DEXA scan) and blood pressure and a blood draw; participants will complete study questionnaires and 10 sleep diaries.

Study questionnaires will collect data on a variety of factors, including participants' demographics and socioeconomic status, cancer diagnosis and treatment, comorbidites and health behaviors, insomnia symptoms, sleep quality, sleep environment and habits, beliefs about sleep, comorbidities, quality of life, depressive symptoms, anxiety symptoms, and cognitive function.

Participants with a compatible Bluetooth-enabled smartphone may be asked to complete an at-home sleep test via a wearable pulse oximeter (i.e., Wesper test kit) and downloaded smartphone application at enrollment and follow-up. Compatible smartphones include iPhone 7 and later modelsup, smartphones that run iOS versions 15 and later, and the latest Android versions (e.g., 12 and later). Only a subset of participants will be consented to this data collection. The service provider for the at-home sleep test is Wesper, Inc. The at-home sleep test kits will be mailed to the servie provider with a prepaid shipping label after use.

The service provider for the actigraphy data is Fitabase/Small Steps Labs LLC. Participants who are not interested in the at-home sleep test may be invited to complete 1 week of wrist actigraphy via a Fitbit Charge 5 at enrollment and follow-up. Only a subset of participants would be consented to this data collection and these participants will keep the Fitbit devices after use.

The study presents minimal risk and requires re-contact, but does not require ongoing monitoring. The intervention is delivered via 6 modules that are released in the program over the course of 6-9 weeks. The intervention program is fully automated with interactive and personalized components; personalization requires that participants input information from sleep diaries. Participants will complete follow-up data collection (i.e., anthropometric measurements, blood pressure, blood draw, study questionnaires, actigraphy) 10-12 weeks after randomization. Participants who complete the follow-up questionnaire will be asked for permission to re-contact them in the future.

Potentially eligible participants' contact information will be collected via medical record review and confirmed or updated during the eligibility screening. Contact information will be retained to facilitate scheduling the follow-up data collection.

7. Study Materials (subject and non-subject facing materials)

Describe and attach copies of any questionnaires, interviews, standardized tests, or any other data collection instruments that are to be used.

Study materials will include study questionnaires, sleep diaries, measurement of anthropometrics, measurement of blood pressure, and a blood draw. Optional study materials will include wrist actigraphy via a Fitbit device, DEXA scan, and an at-home sleep test kit.

III. HUMAN SUBJECTS

1. Subjects

a. Estimated maximum number of local site subjects: 40

b. Estimated maximum number subjects at all sites (including local): 40

c. Age(s) or Age Range: Aged ≥21 years

d. Describe the Target Population: a description of the human subjects who will take part in the study, including members of both intervention/experimental and control groups, if relevant.
Both the intervention and control groups will be comprised of Black adults diagnosed with invasive prostate cancer who have completed active cancer treatment, except for hormone therapy or maintenance therapy, and are experiencing symptoms of insomnia

2. Study Duration for individual subjects

Length of time involved in study. What is the actual burden of time for the individual subject? For example, 1 hour visits every year for a total of three years.

Study enrollment will conducted over 4 months. Participants will take part in the study for a maximum of 12 weeks with two in-person 1-2 hour study visits that take place 10-12 weeks apart, in addition to completing 10 sleep diaries (~2 minutes to complete each). Participants in the intervention group will complete 6 Cores that are expected to take 45-60 minutes to complete over 6-9 weeks, as well as 5 sleep diaries per Core in order to proceed to the next module (~2 minutes to complete each).

3. Criteria for inclusion or exclusion

a. What criteria will be used to include/exclude individuals in/from the study.
Inclusion criteria:
-Aged ≥21 years
-Self-identifies as Black/African American
-Diagnosed with invasive prostate cancer (AJCC stages I-IV) within 5 years
-Completed active treatment (i.e., surgery, chemotherapy, radiotherapy) except hormone therapy or maintenance therapy
-Has a smartphone, tablet, or computer with reliable internet access or willing to attend a weekly study appointment and to complete a weekly phone call
-Has clinically relevant insomnia symptoms (i.e., score ≥10 on the Insomnia Severity Index)
-Able to read and understand English

Exclusion criteria:
-Employed in an occupation where sleep restriction could be a harm to themselves or others (e.g., truck driver, operator of heavy machinery, pilot)
-Actively employed in shift work
-Diagnosed with a severe/major psychiatric disorder
-Diagnosed with a seizure disorder or recently (≤12 months) experienced a seizure
-Unable to consent

b. Are any of these criteria based on race or ethnic origin, age, or gender? If so please explain and justify.
This study is focused on Black prostate cancer survivors, who experience a disproportionate burden of prostate cancer incidence and mortality and insufficient representation in survivorship research.

4. Vulnerable Groups

The Common Rule at 45CFR 46.111(b), and FDA regulations at 21CFR56.111(b), require IRBs to give special consideration to protecting the welfare of particularly vulnerable subjects, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

a. Choose from the following list those vulnerable populations that will be included in this study. Select ALL that apply. If you are not including vulnerable populations select "None".

☒ None (continue to question #5)	☐ Pregnant women
☐ Neonates (newborn less than 4 weeks old)	☐ Children
☐ Prisoners	☐ Mentally disabled
☐ Economically or educationally disadvantaged	☐ Cognitively impaired
☐ Subordinates to one or more investigator	☐ Other:

b. Justify the inclusion of any vulnerable population and why that population is being studied.
n/a

5. Subject recruitment.

Recruitment of subjects must be free of undue influence and coercion.

a. Select ALL recruitment methods that will be used.

☐ Email
☒ Recruitment Letter to Subjects (electronic or print)
☒ Flyer
☐ Record Review
☒ Online/Social Media Advertisement
☐ Newspaper or other Traditional Advertisement
☒ Other: The research nurse at the Office of Minority Health and Health Disparities Research (OMH) will screen medical records from the MedStar Health network.

b. Describe the recruitment methods, including (1) source of subjects; and (2) when, where, and how they will be recruited. Attach copies of recruitment materials, as applicable, in the "Recruitment materials" section of the electronic application.
Clinic: The research nurse at the OMH will screen medical records from the MedStar Health network. The study team will mail invitation letters and study flyers to the home addresses or will e-mail invitation letters to the email addresses listed for potentially eligible patients and will conduct a follow-up telephone call within 2 weeks of the mailing. Interested survivors can also contact study staff for eligiblity screening.
Community: OMH staff will interact with potentially eligible survivors at community outreach and education events.

Clinic: The research nurse will screen electronic medical records for MedStar Health for potential eligibility based on cancer diagnosis (invasive prostate cancer), date of diagnosis (within 5 years), type and date of cancer treatment (completed active treatment except hormone therapy or maintenance therapy), age (≥21 years), race (Black/African American), and additional comorbidities (diagnosis of a severe/major psychiatric disorder, diagnosis of a seizure disorder, recent seizure).
Community: OMH staff will distribute study flyers and introduce the study at OMH events. Interested survivors will contact study staff for eligibility screening.

c. Describe any recruitment methods that are not under direct control of the local investigator (e.g., other site or collaborators are completing some or all of the recruitment methods).

n/a

6. Subject Compensation.

Any payment made must be reasonable in relation to the time and trouble associated with participating in the study. It cannot constitute an undue inducement to participate.

a. Describe any plans to compensate subjects in either cash, gift cards or non-cash item (e.g., gifts, extra credit) including timing of the compensation. If you are not providing compensation state "N/A".
When objective data collection is not available, participants can receive up to $60 via gift card. This amount includes $30 for completeting each study visit and sleep diaries. At study visit #1, participants will receive a reloadable gift card or an e-gift card. Once study staff have confirmed completion of the sleep diaries, $30 will be added to the gift card. For study visit #2, $30 will be added to the gift card after study staff have confirmed completion of the sleep diaries.

When objective data collection is available, participants can receive up to $100 via a gift card. This amount includes $30 for completing each study visit and sleep diaries, $25 for completing at-home sleep testing, and $15 for completing a DEXA scan. Participants who wear a Fitbit will be able to keep it after study visit #2. At study visit #1, participants will receive a reloadable gift card or an e-gift card. For participants who complete a DEXA scan, $15 will be added to the gift card. Once study staff have confirmed completion of the sleep diaries, $30 will be added to the gift card. For participants who participate in at-home sleep testing, $10 will be added to the gift card once study staff have confirmed receipt of the sleep kit. For study visit #2, $30 will be added to the gift card after study staff have confirmed completion of the sleep diaries. For participants who participate in at-home sleep testing after visit #2, $15 will be added to the gift card once study staff have confirmed receipt of the sleep kit.

b. Describe any plans to reimburse subjects for travel or other expenses. If you are not providing compensation for travel or expenses state "N/A".
n/a

7. Potential Risks.

A risk is a potential harm that a reasonable person would consider important in deciding whether or not to participate in research. Risks can be physical, psychological, sociological, economic, or legal, and include pain, stress, invasion of privacy, embarrassment or exposure of sensitive or confidential data. All potential risks and discomforts must be minimized to the greatest extent possible, for example by using appropriate safety measures, monitoring, robust data security measures, and withdrawal of a subject if there is evidence of a specific adverse event.

a. What are the risks or discomforts associated with each interaction, intervention or procedure in the study? Provide a description of the procedures performed to lessen the probability or magnitude of risk. For example, how will undue stress as a result of completing interviews or surveys be minimized?
Tiredness - low to moderate probility, minimal to moderate magnitude; common experience related to sleep restriction required by CBT-I, will be minimized by excluding survivors for whom tiredness could pose a safety risk to themselves or others
Bruising from blood draw - low probability, minimal magnitude; common experience related to venipuncture, will be minimized by calmly explaining the blood draw procedure, working as gently as possible, and, after the blood sample has been taken, applying gentle pressure to the puncture site in order to stop bleeding and minimize potential bruising
Exposure to radiation from DEXA scan - high probability, minimal magnitude; inherent to the procedure, will be minimized by collecting data only at the enrollment visit
Psychological discomfort - low probability, minimal magnitude; will be minimized by using electronic or hard copy study questionnaires, ensuring all staff have human subjects research training, by reiterating that survivors' names will not be connected to their data and that only aggregate results will be presented in public, and by reminding participants that they can skip questions that they prefer not to answer

Loss of confidentiality - low probability, minimal magnitude; will be minimized by ensuring that all staff have human subjects research training, by following Georgetown policies for data management and confidentiality, and by requiring that participant data is treated like PHI by Wesper, Inc. and that this vendor maintains HIPAA compliance

b. Describe whether disclosure of identifiable information about the subjects (even if unintentional or accidental) presents any additional risks to them (e.g., Criminal or civil liability, damage to financial standing, employability, or educational advancement or reputation, or relationships with other people [e.g., family relationships, employer/employee relationships, other]).
It is possible that disclosure of identifiable information could present additional risks due to previously undisclosed information about the cancer diagnosis, symptom burden, and/or genetic information (if blood samples are assayed for genetic information in the future). However, it is anticipated that the risks would be minimal and primarily social/relational in nature.

c. Describe any limitations on confidentiality based on possible reporting issues, for example, if the research team is likely to uncover child, elder or sexual abuse, neglect, or reportable diseases. Please note, the study team will need to disclose this information to appropriate authorities as required by the law.
Note: Please be sure to have the consent form reflect this information as well.
The research team is not likely to uncover reportable offenses or diseases.

d. What follow-up efforts will be made to assess any harm resulting from your study, and under what circumstance would the IRB informed?
No harms are anticipated to result from the study. However, if a participant's report or analysis of study data reveals an increase in symptom burden or any adverse event or unanticipated problem, these findings would be reported to the IRB. The Lombardi Comprehensive Cancer Center Clinical Trials Office Quality Control Unit evaluates protocol compliance and conducts audits of cancer-related clinical trials, which would provide additonal oversight of potential harms.

8. Diagnostic Findings and Referrals

Will referrals to counseling, community-based help or other intervention be offered to subjects if study participation could cause psychological risks or physical risks, if diagnostic findings reveal that a participant may need intervention or treatment, or if it is expected the participant would otherwise benefit from the referral? Please describe why or why not. If a document listing referrals or recommendations of sources of support are to be provided to participants, please include this document in your IRB submission.

Study participation is not expected to cause psychological or physical risks and no incident findings from staff measurement, biospecimen assays, or at-home sleep testing is expected.

9. Potential Benefits.

- Describe the potential benefits to subjects or to others that may be reasonably expected to result from the research. If there is no potential for direct benefit, state this here and include in the informed consent/script.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits and in relation to the importance of the knowledge that may reasonably be gained. Will the research study benefit future populations?
- Compensation for involvement in the research cannot be considered a benefit. Please describe payment in Section 6 only.

a. What potential benefits might the subjects receive from participating in the study?
Participants may experience improvements in their insomnia symptoms and in non-insomnia PROs. It is highly probable that participants who receive SHUTi and engage with the Cores will experience clinically relevant improvements in their insomnia symptoms that may last more than 6 months. Participants who complete at-home sleep testing may benefit from receiving a personalized report from the smartphone app that describes their sleep. This benefit is likely small and of short duration.

There may be no direct benefit to participants who are randomized to sleep education who also do not participate in at-home sleep testing.
Given that anticipated risks are minimal and of low-moderate magnitude and that improvements in sleep may lead to improvements in other health outcomes, the risks to individual subjects are considered reasonable.

b. What potential benefits might **society** expect from the study?
SHUTi has demonstrated efficacy among breast cancer survivors and both the standard version of SHUTi and a culturally-tailored version of SHUTi demonstrated efficacy among middle-aged and older Black women. However, to date, this accessible and interactive intervention has not been investigated among prostate cancer survivors. Thus, the study could uncover opportunities to improve survivorship and possibly reduce racial disparities among prostate cancer survivors. This outcome would benefit future populations of cancer survivors and their communities.

10. Subject Withdrawal

Describe what will happen if subjects voluntarily withdraw from the research. Specify the study milestone at which subjects can no longer withdraw (for example, after they click "submit" on the anonymous survey, or after the data is de-identified). Consider potential negative consequences of withdrawal that would require the participant to follow special procedures to reduce the risk of harm.

We do not anticipate withdrawing participants from the study without their consent. The web-based intervention does not require orderly termination. Any participant who elects to withdraw can immediately discontinue accessing the web portal and contact study staff. Study staff will revoke the participant's access to the web portal within 48 hours of confirming their request to withdraw from the study. However, if a participant withdraws after randomization, the data that they previously provided will contribute toward analyses. No special procedures are expected to be needed in order to reduce risk of harm from withdrawal.

11. Data management and confidentiality

Please review and complete Georgetown University Information Services (UIS) guidance and requirements found in Appendix A. Appendix A is a useful reference in completing this portion of the application.

a. Briefly outline the data analysis that is proposed and who will do it.
Preliminary statistical analysis will assess the distribution of the study variables at baseline and follow-up overall and by intervention group: means (and standard deviations) and medians (and ranges) for continuous variables and frequencies (and percentages) for categorical variables.
We will compare the change in ISI score from the baseline study visit to the follow-up study visit in the intervention group vs. the control group. This analysis will assess mean change in ISI score, as well as insomnia response (i.e., >7 point reduction in ISI score) and insomnia remission (i.e., ISI score <8 at follow-up).
We will also compare change in non-insomnia PROs from the baseline study visit to the follow-up study visit in the intervention group vs. the control group.
All statistical analyses will use SAS 9.4 (SAS Institute Inc., Cary, NC) or R (R Foundation for Statistical Computing, Vienna, Austria).
The preliminary statistical analyses will allow for the detection of outliers, duplicates, and missing data elements. Continuous variables with outliers can be categorized for analysis. Duplicates will not be included in the analyses. Missing variables that factor into indices, like the ISI, will result in a missing value for the index. The missing indicator method can be used for analyses.
Statistical data analyses will be conducted by trained study staff, as appropriate (e.g., the PI, the biostatistician).

b. Where will data be stored? Describe the steps taken to secure the data from the initial point of data collection to the ultimate storage location. Include where and how data will be collected and stored, for how long, who will be responsible for data security, and who will

have access. Will the data be moved in the course of the research? Who (what role) is responsible for managing data integrity?
All electronic data will be stored on our secure servers (GU Box) in a confidential fashion. Subjects will be identified by a study-specific identification number. Links between study ID numbers and identifying information will be password protected. Only the PI and authorized study staff will have access to this information for research purposes. Data will be directly stored in a database with daily network back-ups. Biospecimens will only be evaluated for research purposes and anyone who handles blood samples will not have access to identifying information. All samples will only be linked with a study-specific identification number and the date of the blood draw.

All data collection reports and summaries will be kept in a locked file in the Office of Minority Health and Health Disparities Research. Access to these files will be limited to study team members as authorized by the Georgetown Institutional Review Board. Standard institutional safeguards to protect the data will be followed. All data will be kept in locked file drawers. Access to data files that contain identifying information will be secured with a password filing system and will be restricted to only approved study staff. All project file cabinets and databases will be secured and locked when not in use.

The data will include variables describing participants' questionnaire responses, objective data, and staff-administered measurements. Participants' identifying information will be kept separately from their questionnaire and device data. Participant responses and objective data will be linked to individuals only through a unique identifier and the information used to link records with identifying information will be kept in a securely locked file cabinet only accessible to the study team. Electronic data will be stored in password protected databases on the secure Georgetown server and on Georgetown Box. Identifying information will not be included on datasets used for statistical analysis and study progress reports.

Data collected from questionnaires will be stored on the REDCap database on the Lombardi server and exported to files stored on Georgetown Box; hard copies of completed questionnaires will be stored in labeled file folders in locked cabinets at the OMH. Data from the at-home sleep testing and actigraphy will be stored on Georgetown Box. Biospecimens will be stored frozen at the Tissue Culture & Bio-banking Shared Resource (TCBSR) laboratory. Data and biospecimens will be stored for up to 10 years after the end of the study.

Access to the data will be restricted to the PI and study staff. Access to the biospecimens will be restricted to the PI, study staff, and TCBSR staff. The PI will manage data security and data integrity, with support from the biostatistician.

Data from the at-home sleep kits will be transmitted via Bluetooth from participants' smartphones to the vendor's cloud-based storage system at stored for up to 2 years. Data will be provided to the study team, who will manage the at-home sleep test data alongwith other study data as described above. All study data will be deleted by the vendor at the Principal Investigators' request or after 2 years, whichever is earlier. Participants who complete at-home sleep testing will be asked to delete the smartphone application at the end of the study.

c. If the data will be stored in a repository with the intent to share data with other researchers and/or use the data for future research, describe where and for how long the data will be stored, who can obtain the data, and how data release will be requested and provided.
The data will not be stored in a repository.

d. Which of the following describes the nature of the data (See Appendix B for definitions):

☒ The data will be associated with Personal Identifiers
☐ The data will be deidentified but coded (a code links it to identifiers)
☐ The data will be completely deidentified and not linked to identifiers
☐ The data will be collected anonymously

e. Explain the procedure you will follow, if any, to deidentify the data, and/or to code and record personal identifiers.
A limited data set will be used for analyses. Codes linking participants' identifying information with a study-specific identificaton number in the limited data set will be stored separately from the corresponding data sets.
The data will only be accessed on Georgetown University workstations and lap tops such that encryption and password protection will be in place with two-factor authentication required for access. Access to the data is limited to the PI and study staff. Any study staff added to the project will be approved by the PI and added to the IRB protocol.
Outside vendors – University of Virginia (SHUTi program), Fitabase/Small Steps Labs LLC (Fitbit data), Wesper, Inc.(at-home sleep testing) – will be used and subject to a security review and appropriate contracts and confidentiality agreements. Whereever possible, a study-specific and vendor-specific identification number will be used. For the at-home sleep test, each user account will use an anonymized username, email address, and password. Otherwise, only the minimum amount of personal identifiers required for use of outside vendors will be used.

f. Will any of the identifiable data be Protected Health Information (PHI)? PHI needs to be deidentified in order to comply with HIPAA regulations. (Guidance on deidentification is available here.)
Yes

g. Describe any plans for sharing data outside the study team, including with whom and what will be shared.
The PI will be responsible for receipt and transmission of the data. The project coordinator and TCBSR staff will be responsible for receipt and transmission of the biospecimens. Data sharing with service providers will be restricted to the service contract/scope of work. We do not anticipate additional data sharing.

h. What will happen to the data when the study is completed?
All Georgetown University policies and procedures for data collection, storage, transmission and destruction will be followed.

12. Deception.

If deception will be used to meet the objectives of the study you must clearly describe how the risks to subjects are reasonable in relation to the anticipated benefits. Explain how the study meets the conditions for waiver of alteration of full informed consent.

Will the study use deception to achieve its objectives (deception includes withholding research purpose or design from subjects)?
☐ YES ☒ NO If yes, describe and justify.

13. Consent Process

Documented informed consent is a requirement for all non-exempt human subject research. Templates for informed consent are available on the GU IRB website. Attach copies of the informed consent/assent materials in the Consent Form section of the electronic application. Under certain circumstances the committee may waive the requirement for informed consent. OHRP Informed Consent FAQs

a. Select the consent options you will use during the course of the study. Each selection below must have a description in the subsequent section(s). Choose all that apply:

- ☒ Obtaining Signed Consent (Subject or Legally Authorized Representative)
- ☐ Obtaining Consent Online (**Waiver** of Written Documentation of Consent)
- ☐ Obtaining Verbal Consent (**Waiver** of Written Documentation of Consent)
- ☐ Obtaining Signed Parental Permission
- ☐ Obtaining Signed Assent for Children or Adults Unable to Consent*
- ☐ Waiving Consent and/or Parental Permission (**Waiver** of Consent Process)
- ☐ Obtaining Verbal Assent for Children or Adults Unable to Consent
- ☐ Waiving Assent (**Waiver** of Assent as Assent if Not Appropriate)
- ☐ Other:

*Assent is the agreement of a research subject who is not able to give legal consent to participate. This is usually related to children under the age of 18 years old but can vary by state. Additionally, assent may be appropriate for adults who are unable to consent for themselves. Please see specific recommendation for assent of children and adults here: OHRP Informed Consent FAQs

b. Describe:

- Where the consent process will take place.
- Any waiting period available between informing the prospective subject, subject's Legally Authorized Representative (LAR), or subject's parent about the study and obtaining the consent/parental permission.
- The process for explaining to subjects new risks or study changes during the course of the study.
- What each individual involved in the consent process will do. (Do not include names of the individuals. For example, the study coordinator will provide an electronic copy of consent to subject via email and the PI will explain the study to the subject before proceeding with the intervention)
- The time that will be devoted to the consent discussion.
- Steps that will be taken to minimize the possibility of coercion or undue influence.
- Steps that will be taken to ensure the subjects' understanding.

The consent process will take place at the Office of Minority Health and Health Disparities Research.

Survivors will be offered a 30 minute break to consider providing consent. Survivors will be invited to reschedule the study visit if they would prefer a waiting period of more than 30 minutes.

If new risks or study changes occur during the course of the study, the PI will seek IRB approval for revisions to the informed consent form and, if warranted, a letter to explain new risks and changes to participants and/or a form to re-consent participants in order to continue in the study.

Survivors will arrive at their first study visit, at which time study staff (e.g., the project coordinator) will provide a paper copy of the informed consent form and wil explain the study to the subject. The staff member will describe the study goals and procedures, review the informed consent form, answer any questions asked, and ask the survivor whether they would like additional time to consider participating in the study prior to obtaining signed consent. A maximum of 1 hour will be devoted to the consent discussion, with an additional 30 minute break if the survivor would like additional time to consider the study and ask questions. Participants who will be invited to complete at-home sleep testing will be provided an additional consent form and offered an additional 30 minute break after the consenting study staff member demonstrates the at-home sleep test kit and smartphone application.

The 30 minute waiting period, the option to reschedule the study visit, and demonstration of the at-home sleep test will help reduce coersion and undue influence. In addition, modest compensation is offered to minimize the potential for financial coersion.

To ensure potential participants' understanding, consenting staff will thoroughly review the informed consent form(s) and answer all questions.

c. **For Studies that request an alteration or waiver of the informed consent process:**
If you requested an alteration or waiver of the consent process, including using electronic consent and not documenting written consent: Review the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410 and HRP-411 in the IRB system Library)" and provide sufficient information to justify all criteria needed for approval of a waiver or alteration of consent.
☒ NA
Describe justification:

d. **For studies that will include non-English speaking participants:**
- Reference the IRB policy manual and Procedure MG.O-004.03 — Consenting Non-English Speaking Research Participants.
- Describe if subjects that speak a specific language are the target of the study recruitment. Indicate what languages are understood by prospective subjects and describe the process to ensure oral and written information will be provided in that language.
- If you will not target a specific population that speaks a foreign language but would like to use the short form process, should you encounter a non-English speaking participant, please describe the process you will follow.
- Describe the process you will use for interpretation and documentation of informed consent.
- Include a statement of certification translation or certificate of translation for all translated documents in the "other attachments" section of the electronic application.

☒ NA
Describe:

e. **For studies that include persons under age 18:**
- Describe whether and how parental permission will be obtained and documented from both parents, one parent, or individuals other than parents who can provide permission. (see "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)".)
- Describe whether and how assent will be obtained and documented.

☒ NA
Describe:

f. **For studies that include cognitively impaired adults:**
- Describe the process for determining whether an individual is capable of consent.

☒ NA
Describe:

g. **For studies that include adults who are unable to consent:**
- Review HRP-417 Checklist for cognitively impaired adults, describe and justify all criteria required for approval of the inclusion of adults unable to consent.
- List the individuals from whom permission will be obtained in order of priority.

☒ NA
Describe:

14. Return of Results

Describe if you plan to return individual results to participants and under what circumstances will you or will you not return results. If you are not returning results, justify why. Address how you will handle any incidental findings.

Participants who log in to the SHUTi web portal will receive the results from their sleep diaries; participants who use the at-home sleep test kit will be able to view their sleep reports in the

accompanying smartphone application; participants who use a Fitbit will be able to view their actigraphy data. Individual results from study questionnaires, measurement, or assays will not be returned to participants, as the benefit to the individual is unclear. We do not anticipate any incidental findings with clinical relevance. In the event that an incidental finding with clinical relevance is discovered, we will contact the IRB for permission to re-contact the study participant in order to provide the information.

IV. COLLABORATING or MULTI-SITE STUDIES

1. Is this study a Multi-site or Collaborative study?*

☐ YES ☒ NO (if NO, skip remainder of questions)

*Collaborating Institution(s)

A Collaborating Institution is an institution engaged in portions of the outlined research project.

*Multi-site Study

A multi-site study is a study which follows a single protocol but is conducted in more than one place, each of which is under the direction of one or more separate investigators. (Please Note: A study that utilizes one or more Research Locations at your institution would likely not be considered a multi-site or collaborative research study in this system. Please contact the IRB office for any questions about your study scenario.)

2. Name of Collaborating Institution(s) and/or Site(s) for Multi-Site Studies

List each collaborating institution or Multi-Site Study and indicate the corresponding activities conducted there with the appropriate letter(s) from the list below:

A. The entire protocol will be conducted at the site outside GU (if this is selected no other letters need to be added)
B. Obtain information by intervening or interacting with living individuals for research purposes
C. Obtaining identifiable private information about living individuals
D. Obtaining the voluntary informed consent of individuals to be subjects
E. Making decisions about subject eligibility
F. Studying, interpreting, or analyzing identifiable private information or data/specimens for research purposes
G. Studying, interpreting, or analyzing coded (linked) data or specimens for research purposes
H. Other: please specify

EXAMPLE:
Name: XZY University

Research Activities: B, E, H-the collaborator will recruit participants by review of the EMR at their site and provide to the PI at GU

1. Name of institution:
   Research Activities:
2. Name of institution:
   Research Activities:
3. Name of institution:
   Research Activities:

APPENDIX A

INFORMATION SERVICES GUIDANCE ON DATA STORAGE AND SECURITY

Please complete the following checklists from Georgetown University Information Systems. Definitions of Terms are included below the checklist for your reference and accurate completion.

Indicate in the chart below what type of data is being collected, stored, transmitted, and/or shared.

	Collected	Stored	Transmitted	Shared
Protected Health Information (PHI)	☒	☒	☒	☒
Personally Identifiable Information (PII)	☒	☒	☐	☐
Identified	☒	☒	☐	☐
Deidentified (includes no PHI or PII)	☐	☐	☐	☐
Limited Data Set (LDS	☒	☒	☒	☒
Data from vulnerable populations*	☐	☐	☐	☐

* Pregnant Women, Neonates, Children, Prisoners, Mentally Disabled, Cognitively Impaired, Economically or Educationally Disadvantaged

Address the following data security questions. All "NO" responses require further explanation as to why data security requirements are not being met.

	YES	NO	NA
Computer software is in place to protect against malware (GU employees can visit Georgetown University Software Webstore to ensure you have the appropriate software)	☒	☐	☐
All operating systems and software updates and patches are applied regularly	☒	☐	☐
Data collected is only the minimum data necessary to answer the research question	☒	☐	☐
Codes are stored separately from the corresponding de-identified data	☒	☐	☐
Encryption and password protection are in place on all portable devices used to access data	☒	☐	☐
Two Factor Authentication is used for all systems accessing research data	☒	☐	☐
Any external service/supplier contracts and data use agreements have been reviewed and approved by appropriate institutional offices.	☐	☒	☐
Physical and technical safeguards in place for electronic and paper data during collection, storage, transmission and destruction must be in alignment with Georgetown University/Medstar policies and procedures	☒	☐	☐
Email will not be used to collect, store or transmit sensitive human subject research data or Protected Health Information (PHI)	☒	☐	☐
Secured, non-public Wi-Fi will always be used with this data	☒	☐	☐
Computer screens will be locked when not in use	☒	☐	☐
Data will be securely destroyed at the end of the retention period. (GU policy on secure data destruction)	☒	☐	☐

Explain any "NO" responses here: Contract and agreement have been executed for University of Virginia; others are pending.

Georgetown University Specific Policies

	YES	NO	NA
For surveys, Qualtrics and RedCap– the GU approved survey systems for which we are licensed – will be used.	☒	☐	☐
GU Box will be used as the data storage repository for Research Data	☒	☐	☐
Data will be shared via GU Box or another secure method such as Secure File Transfer Protocol (SFTP). Data will be encrypted during transmission.	☒	☐	☐
I have read and will comply with the UIS Research Data Protections Guidelines	☒	☐	☐

Explain any "NO" responses here:

APPENDIX B

DEFINITIONS

- **Protected Health Information (PHI):**
  Protected health information includes all individually identifiable health information, including demographic data, medical histories, test results, insurance information, and other information used to identify a patient or provide healthcare services or healthcare coverage. 'Protected' means the information is protected under the HIPAA Privacy Rule. Protected health information is defined in the Code of Federal Regulations and applies to health records, but not education records which are covered by other federal regulations, nor records held by a HIPAA-covered entity related to its role as an employer. In the case of an employee-patient, protected health information does not include information held on the employee by a covered entity in its role as an employer, only in its role as a healthcare provider.

  PHI does not include individually identifiable health information of persons who have been deceased for more than 50 years.
  Below is the list of 18 identifiers defined by federal regulations:

  1. Names;
  2. All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
  3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
  4. Phone numbers;
  5. Fax numbers;
  6. Electronic mail addresses;
  7. Social Security numbers;
  8. Medical record numbers;
  9. Health plan beneficiary numbers;
  10. Account numbers;
  11. Certificate/license numbers;
  12. Vehicle identifiers and serial numbers, including license plate numbers;
  13. Device identifiers and serial numbers;
  14. Web Universal Resource Locators (URLs);
  15. Internet Protocol (IP) address numbers;
  16. Biometric identifiers, including finger and voice prints;
  17. Full face photographic images and any comparable images; and
  18. Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)

- **Personally Identifiable Information (PII):**
  The term "personally identifiable information" refers to information which can be used to distinguish or trace an individual's identity, such as their name, social security number, biometric records, etc. alone, or when combined with other personal or identifying information which is linked or linkable to a specific individual, such as date and place of birth, mother's maiden name, etc. (OMB, 2007)

PII can also be a combination of data from which, taken together, the identity of a person can reasonably be known. For example, if the complete birthdate is given as well as the gender, then even the school or street location would be enough to link information provided in a study about an individual to the specific individual. A study subject might disclose private information as part of the study, and/or a study test result might generate private information. In some Human Subjects Research studies, the only identifying information is the consent form or, even without a consent form, the identifying information is that co-subjects in the study observe private information about another co-subject.

PII is protected by state and local data breach laws, and includes:

- Social Security Number
- Place of Birth
- Dependents
- Bank account numbers
- Income tax records
- Driver's license numbers
- Credit card numbers
- Passport numbers

- **Anonymous Data :**
  Data that was collected without identifiers and that were never linked to an individual. Coded data are not anonymous.

- **De-identified Data :**
  The term "de-identified" or "anonymized" should be used only to describe data that:
  - Previously contained identifiers, which have been stripped, and no "code" linking the data back to identifiers still exists, such that the dataset cannot be "re-identified" by anyone.

  Data is not "de-identified," but "coded" and "indirectly identifiable" if:
  - Researchers have "coded" the data and store the code separately from the research dataset, or the data provider has the "key" to "coded" data, even if the researchers do not, or anyone can "re-identify" the data by linking the dataset to direct identifiers.

- **Limited Data Set:**
  A Limited Data Set is a set of data in which 16 categories of identifier have been removed.

  The following identifiers of the study subjects, or of the study subjects' relatives, employers or household members, can be included in a limited data set:

  1. All elements of dates, such as birth date, admission date, discharge date, and date of death;
  2. Town or city, state, and ZIP Code

  The following identifiers of the study subjects, or of the study subjects' relatives, employers or household members, must be removed from a limited data set:
  1. Names;
  2. Addresses, other than town or city, state, and zip code;
  3. Telephone numbers;
  4. Fax numbers;
  5. Electronic mail addresses;
  6. Social security numbers;
  7. Medical record numbers;
  8. Health plan beneficiary numbers;
  9. Account numbers;

10. Certificate / license numbers;
11. Vehicle identifiers and serial numbers (including license plate numbers);
12. Device identifiers and serial numbers;
13. Web Universal Resource Locators (URLs);
14. Internet Protocol (IP) address numbers;
15. Biometric identifiers, including finger and voice prints; and
16. Full face photographic images and any comparable images.